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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,350	11/07/2005	Arvind N Jina	ADCI-010	7209

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,350	JINA, ARVIND N	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-52,91,93 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-52,91,93 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 January 2009 has been entered.

2. Claims 1-39, 53-90, 92 and 95 have been cancelled.

3. Claims 40-52 and 91, 93 and 94 are pending.

4. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-52, 91, 93 and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is vague with respect to recitation of "the second reagent sufficient to capture an analyte of hemoglobin". What makes this reagent *sufficient*? Furthermore, this reagent is not recited as being immobilized in this location, thus it is unclear whether the analyte capture in this area will stay there.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 40-52, 91 and 93-94 rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman (US 4,857,453) in view of Zeuthen et al (US 5,206,144), Law (6,561,581) and Zin (US 6,534,324).

Ullman discloses a device comprising a buffer capsule connected to a sample addition area, a labeling zone and one or more immunosorbing capture zones. See column 22 and figure 1. Ullman teaches that the buffer capsules contain solvent for the sample including detergent,

buffers such as borate, phosphate, tris, etc. See column 14, lines 43-68. The capture agents in the immunosorbing zones are specific binding members including antibodies, biotin, avidin, receptors, DNA, etc. See column 6, lines 1-23.

Ullman differs from the instant claims in failing to teach the detection of an analyte of hemoglobin, nor does Ullman teach a lysing reagent.

Law (6,562,581) however, discloses a flow-through cell for detecting glycated hemoglobin from a blood sample. Law teaches applying an untreated whole blood sample to a sample well, lysing the blood sample with a lysing agent and a buffer, transporting the mixture to a capture zone, binding the glycated hemoglobin with a capture agent, adding a developing solution containing a peroxide and a dye to enable detection of the capture glycated hemoglobin. See column 8, example 5.

Zeuthen discloses the detection of glycated hemoglobin using a monoclonal antibody specific for the same. See column 6, lines 18-30 and 41-54.

And Zin discloses an assay strip comprising a sample addition zone, a conjugate zone, and buffer zone, a capture zone and an absorbent sink at the end. Zin teaches that the buffer zones carries buffers appropriate for the specific assay and can be adapted to the individual analytes. See column 5, lines 50-65. Buffers include Tris, Tween or PBS.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Ullman, for example, to detect glycated and non-glycated hemoglobin such as taught by Law and Zeuthen. The detection of this hemoglobin would necessitate lysis of the blood sample, and at least one of the buffer capsule taught by Ullman would have the obvious choice for the lysing agent taught by Law. The second buffer

capsule would have been expected to contain the elution buffer and a skilled artisan would have had a reasonable expectation of success in choosing the appropriate capture agents for glycated and non-glycated hemoglobin since such agents are well known in the art as demonstrated by Law and Zeuthen. The reference of Zin demonstrates that it is well known in the test strip art to place buffer zones in various locations along the test strip according to the desired sequence of assay.

Furthermore, a skilled artisan would have had a reasonable expectation of success in substituting the reagents taught by Ullman for the antibodies taught by Zeuthen because Ullman teaches that its device may be modified as appropriate for the detection of a variety of analytes and Law and Zither teaches the well known recognition that the level of glycated hemoglobin in a blood sample is a good index for an individual's glycemic control.

A skilled artisan would have been motivated to modify the device of Ullman, for example, to detect glycated and non-glycated hemoglobin such as taught by Law and Zeuthen. Law and Zeuthen clearly teach that glycated and non-glycated hemoglobin may be detected after a sample is treated with a lysing agent and buffer and Ullman and Zin teaches that test strips comprising all necessary reagent for such detection is conventional in the art. Ullman, for example, teaches immunosorbing zones having capture reagents such as antibodies to capture and restrain the analyte in this location for detection via labeled specific binding partners. Therefore, a skilled artisan would have had a reasonable expectation of success in substituting the reagents taught by Ullman for the reagents taught by Law and Zeuthen for the detection of glycated and non-glycated hemoglobin if they desire to detect such an analyte.

With respect to claim 41, Law, Ullman and Zin all teach membranes having capillary functions.

With respect to claim 42, Law teaches lysing agent. And Ullman teaches buffer solution containing detergents capable of lysing RBC. See column 14, lines 65-68.

With respect to claims 43 and 52, Ullman teaches separate buffer capsules containing various buffers. See column 14, lines 34-68.

With respect to claims 44 and 45, Law and Zeuthen teach reagents for capturing glycated hemoglobin. See column 2, lines 59-67 of Law and column 6, lines 18-30 of Zeuthen.

With respect to claims 46-47, Ullman teaches the detection multiple analytes using separate immunosorbing zones. See column 11, lines 43-50.

With respect to claim 48, Law discloses that it is conventional in the art to measure both glycated and non-glycated hemoglobin. See column 2.

With respect to claim 91, Zin discloses a buffer zone disposed downstream of the sample addition zone.

With respect to claim 93, Ullman teaches the detection of analyte at the second location, i.e the detection zone.

With respect to claim 94, Law and Ullman teach the release of eluting agent at the appropriate time.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
March 24, 2009